

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/	MDL DOCKET NO. 1203
FENFLURAMINE/DEXFENFLURAMINE)	
PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO	
SHEILA BROWN, et al.	
v.	
AMERICAN HOME PRODUCTS	
CORPORATION	NO. 99-20593
THIS DOCUMENT RELATES TO:	
Claimant: Michael Ivy	
Claim No.: 183/00 8029576	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

April 8, 2009

Dr. Michael Ivy, a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc. seeks benefits from the AHP Settlement Trust ("Trust"). Under the Settlement Agreement, Matrix Compensation Benefits ("Matrix Benefits") are awarded to compensate claimants for medical conditions caused by the diet drugs, Pondimin or Redux.¹ Dr. Ivy's claim for Matrix Benefits

1. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when diagnosed, and the presence (continued...)

was initially denied by the Trust on July 13, 2006. An Arbitrator issued a Report and Award affirming the Trust's determination on May 21, 2008. The Arbitrator concluded that Dr. Ivy failed to provide the Trust with documentary proof of diet drug ingestion, as required by the Settlement Agreement.

Dr. Ivy has now appealed to this court as permitted under the Settlement Agreement. See Settlement Agreement, § VI.C.4.i. Dr. Ivy argues that he provided sufficient information to the Trust to satisfy his burden of proof. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The decision of this court is final and binding. See Settlement Agreement, § VI.C.4.l.

On June 5, 2002, Dr. Ivy submitted a "Blue Form" to register with the Trust and claim benefits available under the

1.(...continued)
of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease. See Settlement Agreement, §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious valvular heart disease who took the drugs for 61 days or longer and who did not have any of the alternative causes of the disease that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious valvular heart disease who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their heart disease was caused solely by the use of these diet drugs.

Settlement Agreement.² This Blue Form was left substantially blank. The only portions that were completed were those related to the contact information for Dr. Ivy and his attorney. On July 26, 2002, Dr. Ivy's attorney submitted supplemental information regarding his alleged ingestion of the diet drug, Pondimin. According to this Blue Form, Dr. Ivy took Pondimin for 61 days or more and for a total period of time of 6 months to 1 year. It further states that the drug was dispensed from a pharmacy by a pharmacist named Mr. Berwell in Alexandria, Virginia.

Some ten months later, on May 1, 2003, Dr. Ivy submitted another Blue Form. Contrary to the previously submitted Blue Form, this one stated that Dr. Ivy took Pondimin for a period of 5 years. As required under the Settlement Agreement, he also provided a "Declaration of Prescribing Physician or Dispensing Pharmacy," which is dated April 28, 2003 and sets forth that Dr. Ivy prescribed 1 Pondimin pill daily to himself beginning in 1990 and continuing through 1995. Dr. Ivy failed to disclose, as called for in this Declaration, the approximate date in 1990 when he began his ingestion of Pondimin and the approximate date in 1995 when he stopped.

In an October 26, 2004 letter to the Class Counsel Claims Office, Dr. Ivy's attorney explained that Dr. Ivy received

2. The various forms used in the course of registering and applying for benefits under the Settlement Agreement are commonly identified by their color.

samples of Pondimin from company representatives.³ She further explained that Dr. Ivy self-prescribed the drug and ingested the drug samples.

Two years later, on May 30, 2006, the Class Counsel Claims Office advised the Trust that Dr. Ivy's claim should be closed due to his failure to provide the information necessary to complete his claim. According to this letter, the Claims Office attempted to contact Dr. Ivy on three occasions in order to assist him with completion of his claim. On June 26, 2006, Dr. Ivy contested the denial and asserted that he was unable to determine what additional information the Trust needed to complete his claim. He submitted an affidavit with this letter, which declared that he prescribed Pondimin to patients participating in a weight loss program he ran. He also declared that he self-prescribed Pondimin and ingested it once a day from 1990 through 1995 and that he took the drug samples supplied by the representatives of the drug company.

On July 13, 2006, the Trust issued its Final Determination denying Dr. Ivy's claim for Matrix Benefits due to his failure to supply sufficient documentation proving his ingestion of Pondimin. Dr. Ivy appealed this Determination and an arbitration hearing was held. On May 21, 2008, the Report and Award of the Arbitrator affirming the Final Determination of the Trust was issued. The Arbitrator ruled that the affidavit

3. Dr. Ivy's claim was transferred to the Class Counsel Claims Office for processing and evaluation.

submitted by Dr. Ivy in support of his claim for benefits and as proof of his ingestion of Pondimin did not constitute acceptable documentation of diet drug ingestion required under § VI.C.2.d.(3) of the Settlement Agreement. The prescribing physician must identify the claimant, the drug prescribed or dispensed, and the date(s), quantity, frequency, dosage and number of prescriptions or refills issued for the diet drug(s). Dr. Ivy's affidavit failed to set forth the dosage of the diet drug he allegedly dispensed to himself and does not state the quantity, frequency or the number of prescriptions or refills of the diet drug. Accordingly, the Arbitrator concluded that Dr. Ivy failed to supply the required documentation needed to establish his ingestion of Pondimin.

On appeal, Dr. Ivy contends that his affidavit satisfies § VI.C.2.d, which provides:

In order to complete the submission of a Claim and to qualify for any benefits under the Settlement Agreement, each Class Member must submit documentary proof to the Trustees and/or Claims Administrator(s) of the period of time for which the Diet Drugs Pondimin and/or Redux were prescribed and dispensed to the Diet Drug Recipient who is the subject of the Claim. This proof must include one of the following:

- (1) If the diet drug was dispensed by a pharmacy, the identity of each pharmacy that dispensed Diet Drugs to the Diet Drug Recipient, including its name, address, and telephone number, and a copy of the prescription dispensing record(s) from each pharmacy, which should include the medication name, quantity, frequency, dosage and number of refills prescribed, prescribing physician's name, assigned prescription

number, original fill date and each subsequent refill date; or,

(2) If the diet drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the identity of each prescribing physician, including the prescribing physician's name, address, and telephone number and a copy of the medical record(s) prescribing or dispensing the diet drug(s). The medical record(s) must include records which identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and duration the drug was prescribed or dispensed;

(3) If the pharmacy records and medical records are unobtainable, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the Diet Drug Recipient, the drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s).

Settlement Agreement, § VI.C.2.d.

Dr. Ivy argues that his affidavit satisfies subsection (3) above. Although his affidavit does not indicate the dosage for the drug he ingested, he claims that Pondimin was only available in 20 mg dosages and, therefore, his statement that he took one pill daily indicates the dosage. Furthermore, he argues that, despite the requirements of subsection (3), he should not be barred from recovering simply because he cannot recall the precise day and month when he began, as well as stopped, taking the drug.

The Trust contends the Arbitrator correctly concluded that Dr. Ivy failed to satisfy his burden of proving diet drug ingestion in that he failed to describe the dosage, the dates the

drugs were dispensed, and the quantity, frequency, or the number of prescriptions or refills of the diet drug he allegedly prescribed to himself. The Trust further argues that the affidavit submitted by Dr. Ivy to prove his ingestion of the diet drugs lacks credibility and is unreliable. Specifically, the Trust highlights certain ambiguities and inconsistencies in Dr. Ivy's submissions. Significantly, Dr. Ivy submitted a Blue Form in 2002 that stated that he ingested Pondimin for a period of 6 months to 1 year and obtained the drug from a pharmacist, Mr. Berwell, in Virginia. In contrast, his 2006 affidavit states that he ingested the drug intermittently between 1990 and 1995 and obtained the drug from diet drug company representatives.

Given that there are no medical or pharmacy records, Dr. Ivy must rely on his affidavit and his Declaration as the prescribing physician to satisfy his burden of proving diet drug ingestion under § VI.C.2.d. of the Settlement Agreement. Dr. Ivy's inconsistent statements regarding his use of the drug, the length of such usage, and the source of the drug undermine the evidentiary weight of his affidavit. Dr. Ivy fails to explain his inconsistent statements in attesting to one set of facts in 2002 only to attest to a different set of facts in 2006. Given these glaring inconsistencies, we cannot rely on Dr. Ivy's affidavit as proof of his ingestion of the diet drug, Pondimin.

Even if we were able to rely on Dr. Ivy's affidavit, the Arbitrator was correct in holding that it, as well as his Declaration, fail to supply information regarding the date the

drugs were dispensed and the quantity, frequency, and the number of prescriptions or refills he prescribed to himself. We are aware that Pondimin was only available in 20 mg tables and, thus, his Declaration that he took one pill daily satisfies the Settlement Agreement's requirement for information regarding dosage. Physician's Desk Reference 2240 (51st ed. 1997); PTO No. 7066. Nonetheless, the Declaration and affidavit fail to attest to the other required information.

Accordingly, the Arbitrator's award was not clearly erroneous as to his findings of fact, and he did not err as to his conclusions of law. Accordingly, the Report and Award of the Arbitrator will be affirmed.

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Claim No.: 183/00 8029576	:

PRETRIAL ORDER NO.

AND NOW, this 8th day of April, 2009, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the May 21, 2008 Report and Award of the Arbitrator related to the claims of Dr. Michael Ivy for Matrix Benefits under the Nationwide Class Action Settlement Agreement is AFFIRMED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.